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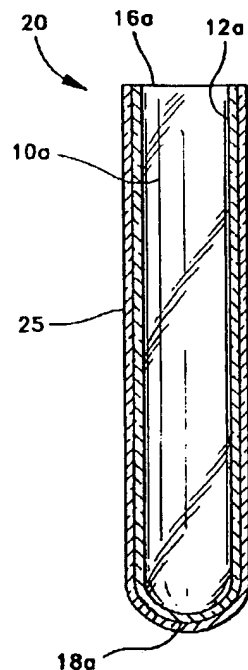
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(54) 【発明の名称】 採血管組立体

(57) 【要約】

【目的】 ポリマーによって作られた製品特にプラスチック製の真空採血管のバリア特性の改良。

【構成】 ダイヤモンド組成物からなるコーティング25が蒸着された、又はダイヤモンドでコーティングしたバリアラベル45によって被覆されたプラスチックの容器10a。ダイヤモンドのコーティングは、容器内への気体の浸透に対して有効なバリアを提供し、容器特にプラスチックの真空採血管の寿命を延ばすのに有用である。



PATENT APPLICATION

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FOR: BLOOD COLLECTION ASSEMBLY

BACKGROUND OF THE INVENTION

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1. Field of the Invention

This invention relates to barrier coatings and  
barrier labels for providing an effective barrier  
against gas and water permeability for containers,  
especially plastic evacuated blood collection tubes.

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2. Description of the Related Art

With the increased emphasis on the use of plastic  
medical products, a special need exists for improving  
the barrier properties of articles made of polymers.

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Such medical products that would derive a  
considerable benefit from improving their barrier  
properties include, but are not limited to, collection  
tubes and particularly those used for blood collection.

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Blood collection tubes require certain performance  
standards to be acceptable for use in medical  
applications. Such performance standards include the  
ability to maintain greater than about 90% original draw  
volume over a one year period, to be radiation  
sterilizable and to be noninterfering in tests and  
analysis.

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A critical performance standard of the blood  
collection tube is the draw volume retention. Draw  
volume retention depends on the existence of a partial

vacuum, or reduced pressure, inside the tube. The draw volume changes in direct proportion to the change in vacuum (reduced pressure). Therefore, draw volume retention is dependent on good vacuum retention.

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For example, it is important to maintain the vacuum over a period of time in order to provide appropriate storage life for those tubes prior to their being used. That is, it is important for the vacuum level to be maintained for a period of time prior to the time when a technician or a nurse uses the tube for collecting a blood sample.

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Radiation sterilizable means that after the tube is exposed to certain levels of radiation in the sterilization process, there is substantially no change in optical or mechanical and functional properties.

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Noninterference in performance of a tube's specifications means that the materials of the tube, such as glass or plastic materials do not interfere with testing and analysis that is typically performed on blood in the tube. Such tests include but are not limited to, hematology, blood chemistry, blood typing, toxicology analysis and therapeutic drug monitoring. Furthermore, the tube must be capable of being subjected to automated machinery such as centrifuges.

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Therefore, a need exists to improve the barrier properties of articles made of polymers and in particular plastic evacuated blood collection tubes wherein such improvement does not obscure the contents of the articles, certain performance standards would be able to be met and the article would be effective and usable in medical applications.

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## SUMMARY OF THE INVENTION

5 The present invention is a plastic composite container coated with a barrier composition or barrier label disposed over an outer surface of the composite container. That is, a barrier composition is coated over the previously formed plastic container or a barrier label coated with a barrier composition is disposed over the outer surface of the composite  
10 container. Such a barrier composition or barrier label improves the barrier properties of plastic containers, does not obscure the contents of the plastic containers and extends the shelf-life of plastic containers, especially plastic evacuated blood collection devices.

15 A desirable barrier composition which can be disposed over a plastic container or a barrier label, preferably comprises a diamond composition. A diamond composition may be applied either to an interior surface  
20 portion or to an exterior surface portion of the container or label.

Desirably, the barrier label may be placed or formed around the container and then adhered to the  
25 container by methods such as, but not limited to, an adhesive layer, heating the barrier label and container to a temperature sufficient to cause the barrier label to heat-shrink onto the container or by expanding the container into the barrier label by blow molding.  
30 Desirably the barrier label of the present invention is a polymer film with a diamond composition coating.

Preferably, the diamond composition provides a transparent, translucent or colorless appearance and may  
35 have printed matter applied thereon.

Plastic tubes or barrier labels coated with the diamond composition are able to maintain far better vacuum retention and draw volume retention than previous tubes comprised of polymer compositions and blends thereof without a barrier coating or label. In addition, the coated or labeled tube's water barrier properties would be significantly improved since diamond coatings are substantially non-polar. Notably is the clarity of the diamond composition, its durability to substantially withstand resistance to impact, abrasion and scratches.

Suitable films to be coated for use as barrier labels according to the present invention include, but are not limited to polypropylene films, low and high density polyethylene films and polyvinylchloride films.

Printing may be placed on the barrier composition or label which is to be used on the container of interest. For example, a product identification, bar code, brand name, company logo, lot number, expiration date and other data and information may all be included on the label surface. Moreover, a matte finish or a corona discharged surface may be developed on the outer surface of the barrier composition so as to make the surface appropriate for writing additional information on the label. Furthermore, another pressure sensitive adhesive label may be placed over the outer surface of the barrier label so as to accommodate various hospital over-labels, for example.

#### DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a typical blood collection tube with a stopper.

FIG. 2 is a longitudinal sectional view of the tube of FIG. 1 taken along line 2-2.

5        FIG. 3 is a longitudinal sectional view of a tube-shaped container similar to the tube of FIG. 1 without a stopper.

10       FIG. 4 is a longitudinal sectional view of a tube-shaped container similar to the tube of FIG. 1 with a stopper.

#### DETAILED DESCRIPTION

15       Referring to the drawings in which like reference characters refer to like parts throughout the several views thereof, FIGS. 1 and 2 show a typical blood collection tube 10, having an open end 16, a closed end 18 and stopper 14 which includes a lower annular portion or skirt 15 which extends into and presses against the inside walls 12 of the tube for maintaining stopper 14 in place. FIG. 2 schematically illustrates that there are three mechanisms for a change in vacuum in a blood collection tube: (A) gas permeation through the stopper material; (B) gas permeation through the tube material and (C) leak at the closure-tube interface. Therefore, when there is substantially no gas permeation and no leak, there is good vacuum retention and good draw volume retention.

30       FIG. 3 shows the preferred embodiment of the invention, a plastic tube coated with a diamond composition or covered by a diamond coated barrier label. The preferred embodiment includes many components which are substantially identical to the components of FIGS. 1 and 2. Accordingly, similar

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components performing similar functions will be numbered identically to those components of FIGS. 1 and 2, except that a suffix "a" will be used to identify those components in FIG. 3.

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Referring now to FIG. 3, the preferred embodiment of the invention, collection tube assembly 20 comprises a plastic tube 10a, having an open end 16a and a closed end 18a. A coating comprising a diamond composition or diamond coated barrier label 25 extends over a substantial portion of the length of the tube which is upon the outer surface of the tube with the exception of open end 16a and closed end 18a thereof.

15 FIG. 4 illustrates an alternate embodiment of the invention, wherein collection tube assembly 40 comprises stopper 48 in place for closing open end 41 of tube 42. As can be seen, stopper 48 includes an annular upper portion 50 which extends over the top edge of tube 42. Stopper 48 includes a lower annular portion or skirt 49 which extends into and presses against the inside walls of tube 42 for maintaining stopper 48 in place and also, defines a well 52 which, in turn, defines a septum portion 53 for receiving a cannula therethrough. Thus, the user, once receiving a container such as that shown in FIG. 4 with a sample contained therein, may insert a cannula through septum 53 for receiving part or all of the contents in tube 42 to perform various tests on a sample.

Covering a substantial portion of the length of the tube is a coating comprising a diamond composition or diamond coated barrier label 45. The coating or barrier label 45 covers substantially most of the tube

with the exception of open end 41 thereof. FIG. 4 differs from the embodiment in FIG. 3 in that the tube may be evacuated with the simultaneous placement of stopper 48 therein after the application of a diamond coating or diamond coated barrier label 45 thereover the tube. Alternatively, the diamond coating or diamond coated barrier label may be applied to the tube before it has been evacuated.

10 An alternate embodiment of the invention also includes a coating or label incorporating both the upper portion of the stopper, as well as the entire container tube. Such an embodiment may be utilized, for example, for sealing the container with the stopper in place. 15 Once a sample has been placed in the tube, the sample cannot be tampered with by removal of the stopper. Additionally, serrations could be included at the tube, stopper interface. The serrations may be registered so that it can be determined if the sealed container has 20 been tampered with.

It will be understood by practitioners-in-the-art, such tubes may contain reagents in the form of additives or coatings on the inner wall of the tube.

25 A coating comprising a diamond composition forms a clear or translucent barrier. Therefore, the contents of a plastic tube coated with a coating comprising a diamond composition are visible to the observer at the same time identifying information may be displayed over 30 the diamond film after it is applied to the plastic tube.

A coating comprising a diamond composition may be formed on a substrate by radio frequency discharge, 35 direct or dual ion beam deposition, sputtering or plasma



chemical vapor deposition, as described in U.S. Patent Nos. 4,698,256, 4,809,876, 4,992,298 and 5,055,318, the disclosures of which are herein incorporated by reference.

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The coating of the present invention is preferably a diamond composition comprising carbon having a major proportion of  $sp^3$  tetrahedral bonding and a minor proportion of  $sp^2$  bonds. In general, the diamond  
10 compositions of the present invention may consist of carbon atoms bonded in a dense chemical structure similar to that in a diamond, but without a long range crystal order.

15

Desirably, the diamond coating is applied to the plastic container or to a barrier film by a dual ion beam ballistic alloy process.

20

A plastic blood collection tube coated with the diamond composition or covered with a diamond coated barrier label may effectively be used in such applications as routine chemical analysis, biological inertness, hematology, blood chemistry, blood typing, toxicology analysis or therapeutic drug monitoring and  
25 other clinical tests involving body fluids.

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If the diamond composition is also coated on the inner surface of the plastic blood collection tube, the diamond coating may be hemorepellent and/or have characteristics of a clot activator.

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It will be understood that it makes no difference whether the plastic composite container is evacuated or not evacuated in accordance with this invention. The presence of a barrier composition or barrier label on

the outer surface of the container has the effect of maintaining the general integrity of the container holding a sample so that it may be properly disposed of without any contamination to the user. Notably is the clarity of the barrier composition or barrier label and their abrasion and scratch resistance.

The diamond coatings or blends thereof used in accordance with this disclosure, may contain conventional additives and ingredients which do not adversely affect the properties of articles made therefrom.

The barrier label is desirably a film coated with a high barrier performance material such as a diamond composition. Preferred film materials include, but are not limited to, polymeric substrate resins. Polymeric substrate resins include, but are not limited to polyamide, polyolefin and polyester. Polyamide includes but is not limited to, biaxial oriented nylon, aromatic amorphous polyamide, polyvinyl chloride and mixtures thereof. Polyolefin includes, but is not limited to biaxial oriented polypropylene, low density polyethylene, polychlorotrifluoroethylene and mixtures thereof. Polyester includes, but is not limited to, polyethylene terephthalate, polyethylene naphthalate, polyethylene isophthalate and mixtures thereof.

WHAT IS CLAIMED IS:

1. A sample assembly comprising:

a plastic tube having an open end, a closed end, an inner surface and an outer surface; and

a coating comprising a diamond composition associated over the outer surface of said tube and extending over a major portion of said outer surface of said tube.

2. The assembly of Claim 1 further comprising a closure in said open end of said tube whereby a container and closure interface is formed.

3. The assembly of Claim 2 wherein said plastic container is a tube and said closure is an elastomeric stopper.

4. The assembly of Claim 3 wherein said tube is evacuated.

5. The assembly of Claim 4 wherein said coating is deposited by radio-frequency discharge, direct ion beam deposition, dual ion beam deposition, sputtering or plasma chemical vapor deposition.

6. A sample assembly comprising:

a plastic tube having an open end, a closed end, an inner surface and an outer surface; and

a coating comprising a diamond composition associated over the inner surface of said tube and extending over a major portion of said inner surface of said tube.

7. A sample container assembly comprising:

a plastic container having an open end, a closed end, an inner surface and an outer surface; and

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a barrier label comprising a polymer film coated with a diamond based composition, associated over the outer surface of said container and extending over a major portion of said outer surface of said container.

8. The assembly of Claim 7 wherein said barrier label comprises a polymer film material selected from the group consisting of polyamide, polyolefin and polyester.

9. A barrier label comprising:

a first layer selected from the group consisting of polyamide, polyolefin and polyester; and

a second layer on said first layer comprising a diamond based composition.

10. A process for the manufacture of a high barrier performance label for use on the outer surface of an evacuated tube, comprising the steps of:

- a) forming a film with a polymeric substrate resin; and
- b) thereafter depositing a diamond based composition to said film by radio-frequency discharge, dual ion beam deposition, direct ion beam deposition, sputtering or plasma chemical deposition.

FIG-1

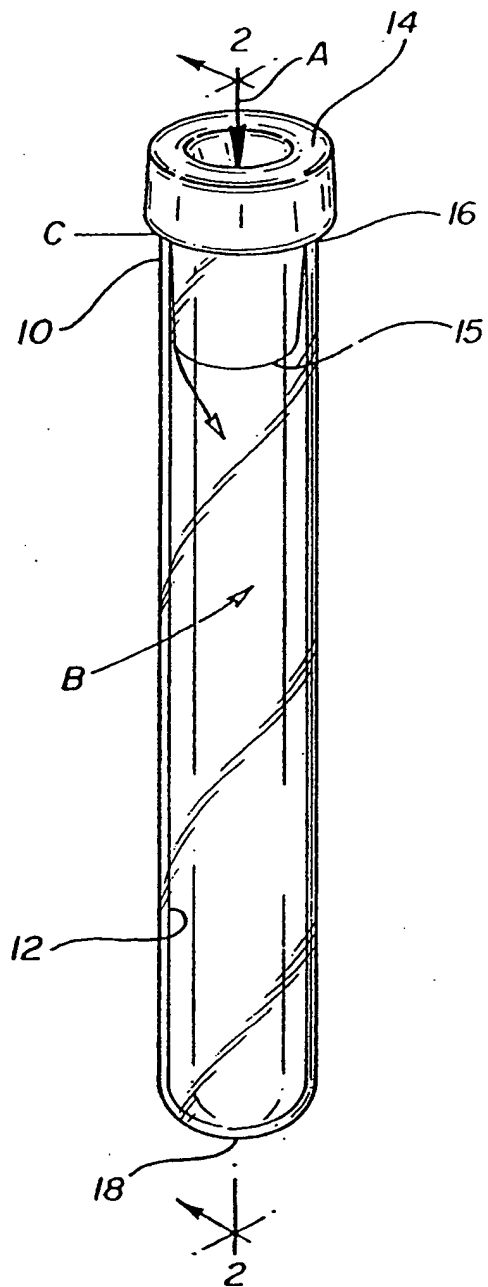


FIG-2

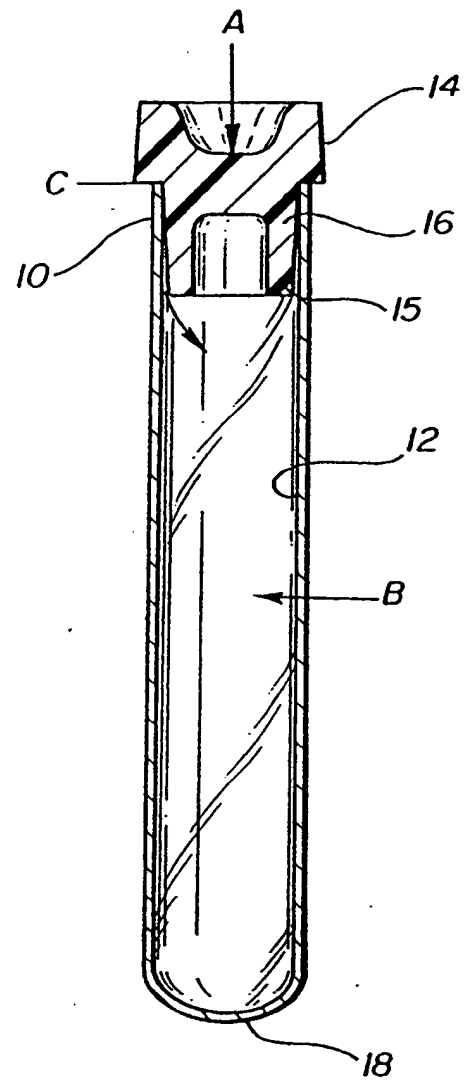


FIG-3

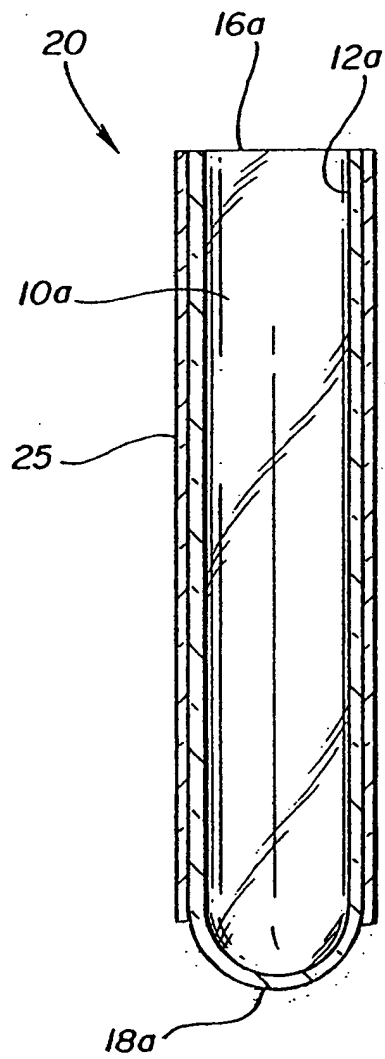


FIG-4

